

Applicant: Faour et al.

Amendments to the Claims

Docket No. PHUS-28

CLAIMS

We claim:

- 1) (Canceled)
- 2) (Canceled)
- 3) (Canceled)
- 4) (Canceled)
- 5) (Canceled)
- 6) (Canceled)
- 7) (Canceled)
- 8) (Canceled)
- 9) (Canceled)
- 10) (Canceled)
- 11) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein the dosage form is selected from the group consisting of a gel, cream, ointment, pill, tablet, capsule, liquid, suspension, osmotic device, bead, granule, spheroid, particulate, paste, prill, reconstitutable solid, powder, caplet, agglomerate, granulate, suppository, enema, bar, plate, pill, and injectible liquid.
- 12) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein the COX-II inhibitor is released at a faster rate than ~~[the muscle relaxant] pridinol~~, or the COX-II inhibitor is released at a slower rate than ~~[the muscle relaxant] pridinol~~ ~~[- or the COX-II inhibitor is released at approximately the same rate as the muscle relaxant when the dosage form is exposed to an aqueous environment].~~
- 13) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein the dosage form provides therapeutically effective plasma levels of the COX-II inhibitor for a period up to at least about 12 hours after administration to a [subject] mammal.
- 14) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein after administration to a [subject] mammal the dosage form provides therapeutically effective plasma levels of ~~[the muscle relaxant] pridinol~~ for a period of administration sufficient to enhance the therapeutic benefit provided by the COX-II inhibitor.
- 15) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein the pharmaceutical dosage form is adapted for oral, buccal, ocular, otic, gastrointestinal, dermal,

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rectal, vaginal, cervical, intrauterine, epidermal, transdermal, implant, mucosal, parenteral, sublingual, nasal, or pulmonary delivery.

16) (Canceled)

17) (Canceled)

18) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein the dosage form provides therapeutically effective levels of each drug for a period of at least 12 hours after administration to a subject.

19) (Original) The pharmaceutical dosage form of claim 18, wherein the period is about 12 to 60 hours.

20) (Original) The pharmaceutical dosage form of claim 19, wherein the period is about 12 to 30 hours.

21) (Original) The pharmaceutical dosage form of claim 19, wherein the period is about 18 to 48 hours.

22) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein after administration to a subject the plasma level of the COX-II inhibitor or [muscle-relaxant] pridinol is dependent upon the plasma level of [the muscle-relaxant] pridinol or COX-II inhibitor, respectively.

23) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein after administration to a subject the plasma level of the COX-II inhibitor or [muscle-relaxant] pridinol is independent of the plasma level of [the muscle-relaxant] pridinol or COX-II inhibitor, respectively.

24) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein the dosage form provides therapeutic plasma levels for [the muscle-relaxant] pridinol in an amount sufficient to provide a therapeutic benefit to a subject to whom it is administered.

25) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein after administration to a [subject] mammal the dosage form provides therapeutic plasma levels for the COX-II inhibitor in the range of about 90 ng to about 300 ng per ml of plasma in the subject.

26) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein the COX-II inhibitor and [muscle-relaxant] pridinol are released sequentially after exposure to an aqueous environment.

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- 27) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein the COX-II inhibitor and ~~[the muscle-relaxant]~~ pridinol are released concurrently after exposure to an aqueous environment.
- 28) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein the COX-II inhibitor and ~~[muscle-relaxant]~~ pridinol are released in spaced apart periods of time after exposure to an aqueous environment.
- 29) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein each drug is independently released according to a controlled, sustained, timed, targeted, pseudo-first order, first order, pseudo-zero order, or zero-order release profile after exposure to an aqueous environment, optionally wherein the release of one or both of the drugs begins after expiration of a lag period, and optionally wherein the release of one drug begins after release of the other drug has begun.
- 30) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein the dosage form provides a controlled release of the COX-II inhibitor and a controlled release of ~~[the muscle-relaxant]~~ pridinol after exposure to an aqueous environment.
- 31) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein the dosage form provides a controlled release of the COX-II inhibitor after exposure to an aqueous environment and a release of ~~[the muscle-relaxant]~~ pridinol within two hours after exposure to an aqueous environment.
- 32) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein the dosage form provides a controlled release of ~~[the muscle-relaxant]~~ pridinol after exposure to an aqueous environment and a release of the COX-II inhibitor within two hours after exposure to an aqueous environment.
- 33) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein the dosage form releases the COX-II inhibitor and ~~[the muscle-relaxant]~~ pridinol within two hours after exposure to an aqueous environment.
- 34) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein the dosage form releases ~~[the muscle-relaxant]~~ pridinol within two hours after exposure to an environment of use and release of the COX-II inhibitor begins after release of ~~[the muscle-relaxant]~~ pridinol has begun.

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- 35) (Previously amended) The pharmaceutical dosage form of claim 34, wherein the dosage form provides a controlled release of the COX-II inhibitor after exposure to an aqueous environment.
- 36) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein the dosage form releases the COX-II inhibitor within two hours after exposure to an environment of use, release of [the muscle relaxant] pridinol begins after release of the COX-II inhibitor has begun.
- 37) (Currently amended) The pharmaceutical dosage form of claim 36, wherein the dosage form provides a controlled release of [the muscle relaxant] pridinol after exposure to an aqueous environment.
- 38) (Canceled).
- 39) (Canceled)
- 40) (Canceled)
- 41) (Canceled)
- 42) (Canceled)
- 43) (Canceled)
- 44) (Canceled)
- 45) (Canceled)
- 46) (Canceled)
- 47) (Canceled)
- 48) (Canceled)
- 49) (Currently amended) A pharmaceutical [composition] dosage form comprising:
- a) a COX-II inhibitor selected from the group consisting of rofecoxib and celecoxib;
  - b) pridinol; and
  - c) at least one pharmaceutical excipient.
- 50) (Currently amended) The pharmaceutical [composition] dosage form of claim 49, wherein the at least one pharmaceutical excipient is independently selected from the group consisting of an acidifying agent, adsorbent, alkalizing agent, antioxidant, buffering agent, colorant, flavorant, sweetening agent, tablet antiadherent, tablet binder, tablet and capsule diluent, tablet direct compression excipient, tablet disintegrant, tablet glidant, tablet lubricant, tablet

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or capsule opaquant, plasticizer, surface active agent, solvent, oil, soap, detergent, and tablet polishing agent.

- 51) (Currently amended) The [composition] dosage form of claim 49, the weight ratio of COX-II inhibitor to pridinol varies from (12.5:2.2) to (50:8).
- 52) (Currently amended) The [composition] dosage form of claim 49, wherein the COX-II inhibitor and pridinol are independently provided in each occurrence in controlled release form, sustained release form, timed release form, or in a form wherein complete release of drug occurs within two hours of beginning of its release.
- 53) (Currently Amended) The [composition] dosage form of claim 52, wherein release of [at least one of the ~~COX-II inhibitor and pridinol~~] the COX-II inhibitor, pridinol, or both begins after expiration of a lag period and/or release of at least one of the COX-II inhibitor and pridinol is targeted in a [subject] mammal to which the composition is administered.
- 54) (Currently amended) The [composition] dosage form of claim 49, wherein [at least one of the ~~COX-II inhibitor and pridinol~~] the COX-II inhibitor, pridinol, or both are independently provided in each occurrence in pseudo-first order, first order, pseudo-zero order, or zero order release form.
- 55) (Currently amended) The pharmaceutical dosage form of claim [10] 49, wherein the COX-II inhibitor and [the muscle relaxant] pridinol are released according to different release profiles when the dosage form is exposed to an aqueous environment.
- 56) (New) The pharmaceutical dosage form of claim 49, wherein the COX-II inhibitor is released at approximately the same rate as pridinol when the dosage form is exposed to an aqueous environment.